

## **REMARKS**

### **Claim Amendments**

Claims 12, 14-19 and new claims 39-40 are pending in the instant application. Claims 15-19 have been withdrawn from consideration. Claim 12 has been amended to remove the term “amino linker” from the list of immunostimulatory moieties, since the amino linker claimed by Applicants is actually a 2-aminobutyl-1,3-propanediol. Claim 14 has been similarly amended to replace the term “an amino linker” with “a 2-aminobutyl-1,3-propanediol linker”. Support for these amendments can be found in the specification in Tables 1 and 2 and Figures 9 and 10. New claims 39 and 40 have been added to further specify that Y is selected from particular recited non-natural pyrimidine nucleosides. Support for claims 39 and 40 can be found in the specification as filed at page 13, lines 6-8. No new matter has been added. Each basis for rejection is separately addressed below.

### **Rejoinder**

Applicants respectfully request that Claims 15-19, previously withdrawn as being directed to non-elected species, be rejoined herein. Claims 15-19 depend from and, thus, require all the limitations of Claim 12.

### **Anticipation Under 35 U.S.C. §102: Ozaki**

Claims 12 and 14 are rejected as being anticipated by Ozaki. Applicants respectfully traverse this rejection. What Ozaki teaches is the replacement of one or more thymidine nucleoside(s) in an oligonucleotide with a uracil nucleoside that has been substituted at the C5 position of the nucleoside base with amino linker arms derived from ethylenediamine (EDA), 1,6-hexanediamine (HMDA) or tris(2-aminoethyl)amine (TAEA). See, in particular, Ozaki at page 1981, right column, first full paragraph, lines 5-10 and Table 1, compounds 5a'-c'. In every case, the nucleoside is still present, but contains one of these base modifications.

In contrast, as shown in Figures 9 and 10, Applicants' claimed 2-aminobutyl-1,3-propanediol linker replaces a nucleoside, i.e., there is no nucleoside present at the position of the 2-aminobutyl-1,3-propanediol linker.

With respect to amended claim 12, the claim requires that the immunostimulatory moiety of any of X, U or D is selected from the group consisting of C3-alkyl linker, 2-aminobutyl-1,3-

propanediol linker,  $\beta$ -L-deoxynucleoside, 1',2'-dideoxyribose, C3-linker, Spacer 18, 3'-deoxynucleoside, 2'-O-propargyl-ribonucleoside, Spacer 9 and 2'-5' linkage, none of which are taught by Ozaki. Thus Ozaki cannot anticipate claim 12.

With respect to amended claim 14, the claim requires that X1 is a naturally occurring nucleoside or an immunostimulatory moiety selected from the group consisting of C3-alkyl linker, 2-aminobutyl-1,3-propanediol linker, and  $\beta$ -L-deoxynucleoside, that X2 is a naturally occurring nucleoside or an immunostimulatory moiety that is a 2-aminobutyl-1,3-propanediol linker, that X3 is a naturally occurring nucleoside or an immunostimulatory moiety that is a nucleoside methylphosphonate, that X4 is a naturally occurring nucleoside or a nucleoside methylphosphonate, that U1 is a naturally occurring nucleoside or an immunostimulatory moiety selected from the group consisting of 1',2'-dideoxyribose, C3-linker, and 2'-O-methyl-ribonucleoside, that U2 is a naturally occurring nucleoside or an immunostimulatory moiety selected from the group consisting of 1',2'-dideoxyribose, C3-linker, Spacer 18, 3'-deoxynucleoside, nucleoside methylphosphonate,  $\beta$ -L-deoxynucleoside, and 2'-O-propargyl-ribonucleoside, that U3 is a naturally occurring nucleoside or an immunostimulatory moiety selected from the group consisting of 1',2'-dideoxyribose, C3-linker, Spacer 9, Spacer 18, nucleoside methylphosphonate, and 2'-5' linkage, that D1 is a naturally occurring nucleoside or an immunostimulatory moiety selected from the group consisting of 1',2'-dideoxyribose and nucleoside methylphosphonate, that D2 is a naturally occurring nucleoside or an immunostimulatory moiety selected from the group consisting of 1',2'-dideoxyribose, C3-linker, Spacer 9, Spacer 18, 2-aminobutyl-1,3-propanediol linker, nucleoside methylphosphonate, and  $\beta$ -L-deoxynucleoside, that D3 is a naturally occurring nucleoside or an immunostimulatory moiety selected from the group consisting of 3'-deoxynucleoside, 2'-O-propargylribonucleoside; and 2'-5' linkage, that each of  $U_m$  and  $D_m$  is a naturally occurring nucleoside or an immunostimulatory moiety, and, finally, that at least one of X1, X2, X3, X4, U1, U2, U3, D1, D2 or D3 is an immunostimulatory moiety, i.e., is one of the immunostimulatory moieties recited for each position.

Thus, when any of X1, X2, X3, X4, U1, U2, U3, D1, D2 or D3 is not a naturally occurring nucleoside, it is not just any immunostimulatory moiety, but one of the immunostimulatory moieties recited for each position. (The final limitation of claim 14 that at

least one of X1, X2, X3, X4, U1, U2, U3, D1, D2 or D3 must be an immunostimulatory moiety does not destroy the limitations in the claim as to what each of those immunostimulatory moieties at each position must be.)

Ozaki does not teach any of the specifically recited immunostimulatory moieties at any of these positions. Thus, Ozaki cannot anticipate claim 14.

Accordingly, Applicants respectfully request that the rejection of claims 12 and 14 as being anticipated by Ozaki be withdrawn.

In addition, new claim 39 depends on, and thus contains all of the limitations of claim 12 and new claim 40 depends on, and thus contains all of the limitations of claims 14. These new claims are simply added to further specify the structure of Y. Thus, new claims 39 and 40 cannot be anticipated by Ozaki.

Obviousness Under 35 U.S.C. §102: Schwartz/Ozaki

As explained above, Ozaki does not teach any of the specifically recited positional modifications of claims 12 or 14. Nor can Ozaki be construed as suggesting any of the claimed positional modifications. Schwartz does not remedy this deficiency of Ozaki, as it also does not teach or suggest any of the specifically recited positional modifications of claims 12 or 14. The currently maintained rejection points out the definition of an immunostimulatory moiety in the specification. However, as explained above, claims 12 and 14 do not allow just any immunostimulatory modification at positions X1, X2, X3, X4, U1, U2, U3, D1, D2 or D3, but requires that the immunostimulatory moiety must be selected from those recited for each position. Since neither Schwartz nor Ozaki teaches or suggests these specifically recited positional modifications, the combination of these references cannot render claims 12 or 14 obvious. Accordingly, Applicants respectfully request that these rejections be withdrawn. Similarly, new claims 39 and 40 cannot be rendered obvious over Schwartz and Ozaki for the same reasons.

Obviousness-type double patenting

Claims 12 and 14 are provisionally rejected for obviousness-type double patenting over various claims of co-pending applications 10/865,245 and 10/694,418. Because these applications are, respectively, later filed or of even filing date with the present application and have not been allowed, once all other presently maintained rejections are overcome, this application should be passed to allowance and any terminal disclaimers or other appropriate actions should be made in the cited applications. See MPEP 804.B.1.

Claims 12 and 14 are also rejected for obviousness-type double patenting over U.S. Patent No. 7,262,286. Claim 1 of this patent recites:

An isolated immunostimulatory oligonucleotide compound, comprising an immunostimulatory dinucleotide of formula C\*pG, wherein the immunostimulatory oligonucleotide compound is at least 6 nucleotides in length, and wherein C\* is a cytidine analog selected from the group consisting of 5-hydroxycytosine, 5-hydroxymethylcytosine, N4-alkylcytosine and 4-thiouracil, G is guanosine, 2'-deoxyguanosine, or a guanosine analog, and p is an internucleotide linkage selected from the group consisting of phosphorothioate, and phosphorodithioate.

Claim 1 of this patent thus does not teach or suggest the positional modifications of claims 12 or 14. For purposes of obviousness-type double patenting, it is only what the claim of the recited reference teaches or suggests that is relevant, not what the specification teaches or suggests. Thus, Applicants respectfully request that this rejection be withdrawn.

**CONCLUSION**

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner believes that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned attorney at 781-933-6630.

Respectfully submitted,

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